

## **REMARKS**

### **1. Status of the Claims**

Independent claims 1 and 31 have been amended to insert the phrase, “wherein said introduction treatment unit moves said magnetic supports and said host relatively to each other in a state where the large number of said magnetic supports in the solution contained in said packing unit are developed in solution by the magnetic force”. This amendment is supported by original claim 3. The insertion of the phrase “in a planar form, and controls so as to move said magnetic supports in the normal direction of the developed surface” in the amended claims 1 and 31 is supported by the description on page 12, lines 4 to 21, and Figure 2, particularly, the description on page 12, lines 11 to 13. Original claim 3 has been cancelled so as to avoid duplication.

### **2. Claim Rejections - 35 U.S.C. § 112**

Claims 1-18, 31-36 and 41 have been rejected under § 112, second paragraph as being indefinite. This rejection is respectfully traversed.

The Examiner asserts that the term “large” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of invention. However, as is clear by amended claim 1 *per se*, as well as the description at page 12, lines 11 to 21 and Fig. 2, the term “large” relates to the number of magnetic supports in the solution contained in the packing unit that are developed in solution by the magnetic force, in a planar form for being densified more than the surroundings so as to partition the packing unit. The supports are controlled so as to move them in the normal direction of the developed surface. One of ordinary skill can determine the degree of “large” by taking into account the size of the magnetic supports (for example, about between 100nm and 200nm at page 5, line 28 in the specification of the present application) or between 1µm and 2µm (on page 6, line 1 in the specification of the present application) and the size of the packing unit and amount of liquid.

Furthermore, the Examiner asserts that one's conception of "large" may be based either on total quantity or concentration. It is clear from the above that the term "large" modifies the term "number of said magnetic supports" and that the magnetic supports in a planer form are densified more than the surroundings as discussed above.

### **3. Claim Rejections - 35 U.S.C. § 102**

Claims 1 and 4-8 have been rejected under 35 U.S.C. 102 (b) as being anticipated by Chan (US 5753477). This rejection is respectfully traversed.

In spite of the passages pointed out by Examiner (i.e. column 5, line 42 to column 6, line 59, column 4, lines 32-62), Chan does not disclose disposition of the container and magnet(s) nor does Chan disclose that the introduction treatment unit which controls a magnetic force should affect the inside of said packing unit from at least two directions with said packing unit therebetween so as to move said magnetic supports relative to said host in solution to introduce the biological material into the host, as recited in amended claim 1. Chan only discloses that a microparticle, coated or not coated, is pulled into the cell using a single strong magnetic pulse or multi-pulses of moderated field strengths (see column 4, lines 39 to 42 of Chan). Hence, with Chan, the microparticles instantaneously collide with the wall of the packing unit and the microparticles are adsorbed to the wall or aggregated on the wall.

In contrast thereto, the present invention avoids, this adsorbed or aggregated state of the microparticles as described in Chan. This is done in the present invention to increase the chance of collision or encounter between the magnetic supports and the host suspended in the solution. For this purpose, with the present invention, the large number of magnetic supports in the solution contained in the packing unit are developed in solution by the magnetic force controlled in at least two directions, in a planar form and with controls so as to move the magnetic supports in the normal direction of the developed surface, as described in amended claim 1 and the specification at page 12, line 4 to 10. Therefore the present invention is not anticipated by Chan.

**4. Claim Rejections - 35 U.S.C. § 103**

**4.1. Chan in view of Dzekunov**

Claims 2, 3, 9, and 31-36 have been rejected under 35 U.S.C. 103 (a) as being unpatentable over Chan (US5753477) in view of Dzekunov et al. (US 20030073238).

The Examiner asserts that Dzekunov et al. discloses a flow cell adapted for the transfection of biological cells with foreign matter, a flow channel (Figure 13:40) is provided in communication with electrode plates (Figure 13:10) configured to create an electrical field capable of porating a cell (paragraph 0249), and that paragraph [0199] and [0200] indicate that the operation of the system is regulated using a control unit.

However, the control unit of Dzekunov et al. which controls an electrical field for electroporation of a cell is distinct from the control unit which controls a magnetic force affecting the inside of said packing unit from at least two directions with said packing unit therebetween so as to move said magnetic supports relative to said hosts in solution to introduce said biological material into said host, and which moves said magnetic supports and said hosts relative to each other in a state where a large number of said magnetic supports are developed in solution by the magnetic force, in a planar state and which controls the unit so as to move said magnetic supports in the normal direction of the developed surface, as recited in amended claim 1.

Therefore, since there is no disclosure of this control unit of the present invention in Chan et al. or Dzekunov et al., a person of ordinary skill would not be lead to the present invention, even with a combination of the cited references.

In accordance with amended claim 1, the number of collisions or the rate of collision, and the chance of encounter of the magnetic supports are increased by causing relative movement between the magnetic supports and the host in a state where the magnetic supports are developed in the solution in the packing unit. Therefore, attachment due to collision with the packing unit is avoided, and the magnetic support layer is formed. Hence the number of collisions, the rate of

collisions, or the chance of encounter with the magnetic support can be more widely increased by means of the invention (see page 12, line 24 to page 13, line 2 in the present application).

The present invention has significant improved effects over Chan et al. and Dzekunov et al. Therefore, it would not have been obvious for a person of ordinary skill in the art to obtain the present invention based on Chan et al. and Dzekunov et al. Consequently, claims 2, 4-12, 14-18, 32-36 dependent upon claim 1 or claim 13 are not obvious, either.

#### 4.2. Chan in view of Dzekunov and Lafferty

Claims 10-16 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5753477) as applied to claim 1, and further in view of Lafferty (US 20030096220). This rejection is respectfully traversed.

The Examiner recognizes that Chan does not expressly indicate that a plurality electromagnets are provided in communication with a transfer element for movement around the packing unit. However Lafferty does not teach this deficiency in Chan. Although Lafferty discloses a capillary device for screening biological analytes with a plurality of magnets capable of interacting with magnetic beads within the capillary device, and teaches a plurality of magnet blocks capable of being mechanically moved up and down the capillary, the magnetic particles of Lafferty are not developed in a planar form, in the direction normal to the moving direction of the magnetic particles between the bottom and top of the capillary as the present invention. Hence the control of magnetic particles of Lafferty is distinct from that of the present invention.

Therefore, the rejection based on Lafferty should be withdrawn.

#### 4.3. Chan in view of Dzekunov and Blankenstein

Claims 17, 18 and 41 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 5753477) as applied to claim I, and further in view of Blankenstein (US 20030044832). This rejection is traversed.

The Examiner recognizes that Chan does not expressly indicate that a magnetic separation unit is provided for isolating magnetic particles. However Blankenstein cannot make up for this deficiency in Chan. Although Blankenstein discloses a magnetic separation unit comprising a packing unit through which magnetic supports (Figure 1:12) and non-magnetic particles (Figure 1: 13) are allowed to flow and a magnet (Figure 1:8) is provided for separating the magnetic supports from the remainder of the mixture solution by causing the magnetic supports to deviate toward a different fluid outlet (Figure 1:6, paragraph [0132] ), the magnetic particles of Blankenstein are not developed in a planar form, in the direction normal to the moving direction of the magnetic particles by the magnetic force.

Accordingly, the Examiner has failed to establish a *prime facie* showing of obviousness.

## **5. Conclusion**

As discussed above, the apparatus in the present application is distinct from the apparatus or method of the cited references. Due to these differences, the apparatus of the present invention has remarkable advantages over any apparatus or method of the cited references, particularly with respect to the increased number of collision or the rate of collision, and the chance of encounter of the magnetic supports, thereby making relative movement between the magnetic supports and the host in a state where the magnetic supports are developed in the solution in the packing unit, and avoiding attachment due to the collision with the packing unit. Therefore, a person of ordinary skill in the art would not find the present invention obvious over the cited references.

Therefore, the rejections in the Office Action should be withdrawn.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a one (1) month extension of time for filing a reply in connection with the present application, and the required fee of \$65.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson Reg. No. 30,330 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By 

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